

Remarks

At the outset it is noted that a shortened statutory response period of three (3) months was set forth in the June 22, 2009 Official Action. Therefore, the initial due date for response was September 22, 2009. Accordingly, a petition for a 1 month extension is presented with this response, which is being filed within the two month extension period.

Claims 1-4, 13, and 17-20 have been rejected under 35 U.S.C §102(b) for allegedly being anticipated by WO 99/36050.

The Examiner has also rejected claims 9 and 29 under 35 U.S.C §103(a) as allegedly unpatentable over the '050 application.

Lastly, claims 1-4, 9, 13, 17-20, and 29 have been rejected under 35 U.S.C §103(a) as allegedly unpatentable over WO 99/04752 in view of Kunitz (J. Gen. Physiol. (1946) 29:149-154).

The foregoing rejections constitute all of the grounds set forth in the June 22, 2009 Official Action for refusing the present application.

No new matter has been introduced into this application by reason of any of the amendments presented herewith.

In view of the present amendment and the reasons set forth in this response, Applicants respectfully submit that the 35 U.S.C. §102(b) rejection of claims 1-4, 13, and 17-20; and the 35 U.S.C. §103(a) rejections of claims 1-4, 9, 13, 17-20, and 29, as set forth in the June 22, 2009 Official Action, cannot be maintained. These grounds of rejection are, therefore, respectfully traversed.

CLAIMS 1-4, 13, AND 17-20 ARE NOT ANTICIPATED BY WO 99/36050

Claims 1-4, 13, and 17-20 have been rejected under 35 U.S.C §102(b) for allegedly being anticipated by WO 99/36050. The '050 application allegedly discloses using soy extracts for protecting skin from UV damage. It is also the

Examiner's position that the soy extract is non-denatured because the soy beans are allegedly extracted without using enzymes or temperature. Applicants respectfully disagree with the Examiner's position for the reasons of record and those set forth below.

At the outset, Applicants are disappointed that the Examiner has changed his mind regarding the patentability of the instant claims in view of the '050 application. Indeed, in the January 21, 2009 Official Action, the Examiner determined that claim 33 (whose features are now recited in claim 1) was not anticipated by the '050 application.

At page 3 of the instant Official Action, the Examiner states that the '050 application "explicitly teaches that the extract may be prepared according to WO 93/23069. Then '050 goes on to explicitly state, the soy extract is done by a mixture of organic solvents (such as ethanol) and water, without any disclosure of application of heat." Applicants respectfully disagree. The actual passage at page 11 of the '050 application is: "**As described in W093/23069** soy or clover may be extracted with a mixture of organic solvent (such as ethanol, chloroform, acetone, ethyl acetate and the like) and water" (emphasis added). Accordingly, the '050 application is still referring to the methods in the '069 application for preparing the extracts of soy and clover. Moreover, the only method of preparing an extract actually exemplified and performed in the '050 application is the generation of a red clover extract "prepared according to WO 93/23069" (page 11, line 26). Thus, the **only** method of preparing an extract disclosed by the '050 application is the method of the '069 application.

Turning to the '069 application, which describes the only method of preparing a soy extract in the '050 application, it is clear that the '069 application requires denaturing heat. Indeed, at Example 2 (pages 18-19), the '069 application states that the "soybeans were heated in dry air so that the hull became brittle." At pages 3-4 of the instant

Official Action, the Examiner asserts that the '069 application "applies heat to make the hull brittle, not to heat the cotyledons or hypocotyls. No evidence is presented which suggests heating of the hull to ease hull removal will cause denaturing of the product within the hull." Applicants respectfully disagree. U.S. Patent No. 4,556,573 at column 1 describes a conventional method for removing the hull of a soybean. Notably, the soybeans are heated to around 90°C and then maintained at "approximately 10°C above the ambient temperature" for at least 48 hours in order to render the hulls brittle prior to splitting in a tumble mill (column 1, lines 25-36). Such extreme heat is clearly sufficient to denature soy product, particularly the Kunitz-type soybean trypsin inhibitor. Indeed, the instant application teaches that the Kunitz-type soybean trypsin inhibitor is readily denatured by heat. Further, Table 1 of U.S. Patent Application No. 10/108,248 (now U.S. Patent No. 7,309,688), from which the instant application depends, demonstrates that soymilk heated to 100°C for only ten minutes does not have the anti-tumor properties of non-denatured soymilk due to the inactivation of the Kunitz-type soybean trypsin inhibitor.

At page 4 of the instant Official Action, the Examiner also states, regarding the '069 application, that "once the hull is removed, Example 2 does not teach how to extract, apparently relying on the process of Example 1, which specifically teaches the use of an organic solvent mix." Turning to Example 1, the '069 application specifically states that the isoflavone extract is obtained by exposing "the plant material to the water:solvent mix" (page 18, line 10). However, the '069 application further teaches that "the exposure time in general terms is indirectly proportional to the temperature of the mixture" and that it "has been determined that the adequate times for maximal recovery of isoflavones are 2 weeks at 50°C and 24 hours at 90°C" (page 18, lines 10-16). Accordingly, the '069 application specifically teaches creating a soy extract by extreme heating

for a prolonged period of time. Clearly, the soy extract is denatured and any Kunitz-type soybean trypsin inhibitor contained therein would be denatured, in complete contrast to the instantly claimed invention.

As stated in the previous Official Action responses, the Examiner is reminded that the '050 application and the '069 application are concerned with using the isoflavone compounds contained within soy or clover (see Abstract and claims). In complete contrast to the Kunitz-type soybean trypsin inhibitor, isoflavones are not proteins. Rather, isoflavones are small chemical compounds which are well-known to be resistant to heat which denatures proteins. Accordingly, a skilled artisan, apprised of the '050 and '069 applications, *would not have any motivation in omitting the heating steps* described in the purification methods in these applications. Indeed, contrary to the position of the Examiner, a skilled artisan would have every reason to include the heat denaturation steps described in the '050 and '069 applications because these applications assert that the isoflavone of soy is the desired compound and a skilled artisan would seek to remove other soybean contaminants such as proteins.

In view of all of the foregoing, it is without question that: 1) the '050 application discloses only one way to produce a soy extract (the method of the '069 application); 2) the '069 application describes one way of preparing an isoflavone containing extract of soybean and the method comprises at least two stages of extreme, protein denaturing heat; and 3) the '050 and '069 applications teach that the isoflavones of soy, which cannot be denatured by heat, are the desirable component. Accordingly, it is evident that the '050 application only discloses denatured soy products, in complete contrast to the instantly claimed invention.

It is a well-settled premise in patent law that in order to constitute evidence of lack of novelty under 35 U.S.C. §102, a prior art reference must identically disclose

each and every element of the rejected claim. In re Bond, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). The '050 application does not teach a non-denatured soy product for the reasons set forth above. As such, the instant rejection under 35 U.S.C. §102 is clearly untenable and Applicants respectfully request its withdrawal.

As an additional matter, the Examiner states at page 3 of the instant Official Action that the "process specifically disclosed by '050 is not limited by the disclosure of '069, but instead the specific teaching of '050 is directed to the use of organic solvents used to extract the product, with no teaching that heat must be applied." Applicants disagree with the Examiner's for the reasons set forth hereinabove. The '050 application provides a single method for preparing a soy extract - the method provided in the '069 application. As explained above, the extraction method of the '069 application requires two steps of denaturing heat, including during the extraction with a mixture of organic solvent and water. For the reasons set forth above, the heat is desirable to eliminate the other components of the soy, including proteins such as the Kunitz-type soybean trypsin inhibitor. Inasmuch as the heat denaturation is desirable in the methods of the '050 and '069 applications and the '050 and '069 applications only describe extracts made by processes involving heat denaturation, these applications are clearly limited to heat denaturation in the absence of a direct teaching to the contrary. Obviously, the '050 application is void of any such statement. In complete contrast, the instant application clearly demonstrates the presence of a beneficial, heat-sensitive protein in soybean (the Kunitz-type soybean trypsin inhibitor) and teaches a skilled artisan to use non-denatured soy products. It is only with impermissible hindsight reconstruction that the Examiner can set forth the position that the '050 application encompasses non-denatured soy products.

Inasmuch as the '050 application does not teach a

non-denatured soy product, it is evident that the rejection of claims 1-4, 13, and 17-20 under 35 U.S.C §102(b) is untenable. Withdrawal of the rejection is respectfully requested.

CLAIMS 9 AND 29 ARE NOT RENDERED OBVIOUS BY WO 99/36050

The Examiner has rejected claims 9 and 29 under 35 U.S.C §103(a) as allegedly unpatentable over WO 99/36050. The Examiner states that the '050 application "does not disclose the instant emulsifier range from about 0.1 to about 20%." However, it is the Examiner's position that it would have been obvious to a skilled artisan to use an emulsifier in the claimed range. Applicants continue to respectfully disagree with the Examiner's position for the reasons of record and those set forth herein.

As stated hereinabove, the '050 application, as evidenced by the '069 application, only teaches or suggests the use of a heat denatured soy product (i.e., an extract containing isoflavones). Inasmuch as the extraction methods described in the '050 and '069 applications include heat denaturation and the '050 and '069 applications teach the desirability of a compound which cannot be denatured by heat, it is evident that the '050 application fails to teach or suggest the use of a non-denatured soy product as instantly claimed.

In view of the foregoing, it is clear that the instant rejection of claims 9 and 29 under 35 U.S.C §103(a) is untenable. Withdrawal of the rejection is respectfully requested.

**CLAIMS 1-4, 9, 13, 17-20, AND 29 ARE NOT RENDERED OBVIOUS BY
WO 99/04752 IN VIEW OF KUNITZ**

Claims 1-4, 9, 13, 17-20, and 29 have been rejected under 35 U.S.C §103(a) as allegedly unpatentable over the '752 application and Kunitz. The '752 application allegedly discloses the application of a soybean trypsin inhibitor. The Examiner contends that while the '752 application does not

specifically teach the administration of a non-denatured Kunitz-type soybean trypsin inhibitor, it would have been obvious to use such an inhibitor in view of Kunitz.

Applicants respectfully disagree with the Examiner's position for the reasons of record and those set forth herein. The '752 application describes methods and compositions for bringing about changes in skin pigmentation and affecting melanogenesis. In stark contrast, the instant claims recite A methods of "reducing the risk of cutaneous tumor development in skin cells that have not yet been damaged by ultraviolet radiation." The '752 application and Kunitz wholly fail to teach or suggest that the administration of a non-denatured soy product would have any benefit in reducing the risk of cutaneous tumor development. In fact, the '752 application teaches away from the instantly claimed invention. Indeed, as demonstrated in Figure 1B, the '752 application discloses that soybean trypsin inhibitor (STI) is "particularly" effective in inhibiting melanogenesis, the process by which melanin is made. Significantly, as of the effective filing date of the instant application, the skilled artisan understood melanin provided protection for skin from harmful ultraviolet radiation. For example, Gilchrest et al. (N. Eng. J. Med. (1999) 340:1341-1348) teach that "poorly melanized skin is far more vulnerable than melanized skin to acute and chronic injury caused by ultraviolet radiation (sunburn and photoaging or *photocarcinogenesis...*)" (page 1343, left column; emphasis added). Gilchrest et al. further state that melanin "has a photoprotective function in the skin, directly absorbing ultraviolet photons as well as reactive oxygen species generated by the interaction of ultraviolet photons with membrane lipids and cellular chromophores" (page 1343, left column). Notably, melanin levels are increased in response to ultraviolet injury of skin which results in "a long-lasting endogenous "sunscreen" with a measured sun protection factor of approximately 3 to 5" (page 1343, left column). Moreover, other studies have shown that the increased levels of melanin

in dark skin reduces the amount of ultraviolet radiation that reaches the upper dermis 5 fold and reduces the risk of skin cancer 500-1000 fold when compared to Caucasian skin (see, e.g., the abstracts of Kaidbey et al. (J. Am. Acad. Dermatol. (1979) 1:249-260) and Kollias et al. (J. Photochem. Photobiol. B. (1991) 9:135-160)).

In view of the foregoing, it is evident that the skilled artisan understood that increased melanin levels protected skin from ultraviolet radiation and reduced cutaneous tumor development. However, the '752 application teaches that STI administration decreases the levels of melanin. This is a *direct teaching away* from the instantly claimed methods. Indeed, in view of the above, a skilled artisan - apprised of only the '752 application - would have determined that the administration of an STI would have increased the risk of cutaneous tumor development in skin cells, in complete contrast to the instantly claimed methods.

Inasmuch as the '752 application directly teaches away from the instantly claimed methods, it cannot be reasonably held that the instant claims are rendered obvious by the disclosures of the '752 application and Kunitz. In view of all of the foregoing, Applicants submit that the rejection of claims 1-4, 9, 13, 17-20, 29, and 33 under 35 U.S.C §103(a) cannot be reasonably maintained. Withdrawal of the rejection is respectfully requested.

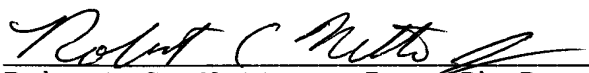
CONCLUSION

In view of the foregoing remarks, it is respectfully urged that the rejections set forth in the Jun 22, 2009 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the

Examiner is requested to telephone the undersigned attorney at the phone number given below.

Respectfully submitted,
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Enclosures: Gilchrest et al., N. Eng. J. Med. (1999) 340:1341-1348

Kaidbey et al., J. Am. Acad. Dermatol. (1979)
1:249-260 (Abstract)

Kollias et al., J. Photochem. Photobiol. B. (1991)
9:135-160 (Abstract)